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| APPLICATION NO.             | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------|-------------|----------------------|---------------------|------------------|
| 10/791,270                  | 03/03/2004  | Masaaki Nomura       | 100598.53322US      | 8940             |
| 23911                       | 7590        | 03/17/2009           | EXAMINER            |                  |
| CROWELL & MORING LLP        |             |                      | AHMED, HASAN SYED   |                  |
| INTELLECTUAL PROPERTY GROUP |             |                      |                     |                  |
| P.O. BOX 14300              |             |                      | ART UNIT            | PAPER NUMBER     |
| WASHINGTON, DC 20044-4300   |             |                      | 1615                |                  |
|                             |             |                      |                     |                  |
|                             |             |                      | MAIL DATE           | DELIVERY MODE    |
|                             |             |                      | 03/17/2009          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/791,270             | NOMURA ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | HASAN S. AHMED         | 1615                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 19 December 2008.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-14 and 16-23 is/are pending in the application.  
 4a) Of the above claim(s) 9,10,12,14,16 and 23 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-8,11,13 and 17-22 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

- Receipt is acknowledged of applicants' response to notice of non-compliant amendment, filed on 19 December 2008.
- Applicants' remarks, filed on 14 March 2008 have been considered but are moot in view of the new grounds of rejection.

\* \* \* \* \*

### *Election/Restrictions*

Applicants' election without traverse of species I(e) and II(b) in the reply filed on 19 December 2008 is acknowledged.

Claims 9, 10, 12, 14, 16, and 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 19 December 2008.

It is noted that Groups I and II of the restriction requirement of 2 May 2007 have been rejoined with this Office action.

\* \* \* \* \*

### *Claim Objections*

Claim 18 is objected to because of the following informalities: claim 18 partially depends from withdrawn claim 16. Appropriate correction is required.

\* \* \* \* \*

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-3, 5-7, 18, and 19, are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 2004/0022844 ("Hasenzahl").

Hasenzahl teaches granular pharmaceutical compositions (see paragraph 0001) comprising:

- the hard capsule of instant claim 1 (see claim 3);
- the inorganic substance (silicone dioxide) contained with penem antibiotic (e.g. faropenem) of instant claim 1 (see paragraph 0119 and 120);
- the gelatin based hard capsule of instant claim 2 (see claim 3);
- the silicon dioxide of instant claim 3 (see paragraph 0119);
- the inorganic substance concentration (e.g. 5 to 25 wt. %) of instant claims 5, 18, and 19 (see paragraph 0017);
- the solid or semisolid form of instant claim 6 (see paragraph 0117); and
- the granule (e.g. granulates or powders) of instant claim 7 (see paragraph 0117);

Although Hasenzahl does not provide an explicit example of the formulation being claimed, the reference discloses every element of the formulation disclosed in claims 1-3, 5-7, 18, and 19 in the same configuration as claimed (see above).

Hasenzahl explains that the disclosed composition provides improvements in the bioavailability of sparingly soluble medicaments and protects active agents from environmental insults (see paragraph 0005).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a hard capsule in which an inorganic substance is contained with a penem antibiotic, as taught by Hasenzahl. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it provides improvements in the bioavailability of sparingly soluble medicaments and protects active agents from environmental insults, as explained by Hasenzahl (see above).

\*

2. Claims 1 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 2004/0022844 ("Hasenzahl") in view of DE 101 44 557 ("Bruck").

Hasenzahl teaches granular pharmaceutical compositions (see above).

Hasenzahl differs from the instant application in that it does not teach the compound of instant claim 17 (faropenem daloxate). However, use of faropenem daloxate in controlled release oral formulations was known in the art at the time the instant application was filed, as evinced by Bruck (see, e.g., page 1, EPO machine translation, attached).

Bruck explains that use of faropenem daloxate is beneficial compared to other beta lactams, because it is absorbed in the deep intestine section, including the colon (see, e.g., page 1, EPO machine translation, attached).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a hard capsule in which an inorganic substance is contained with the penem antibiotic faropenem daloxate, as taught by Hasenzahl in view of Bruck. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it results in absorption in the deep intestine, as explained by Bruck (see above).

\*

3. Claims 1, 8, 11, 13, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 2004/0022844 ("Hasenzahl") in view of U.S. 2005/0004155 ("Boyd").

Hasenzahl teaches granular pharmaceutical compositions (see above).

Hasenzahl differs from the instant application in that it does not teach drug with a functional coating (instant claim 8), mixtures of drug with a functional coating and without a functional coating (instant claims 11, 20, and 21), and mixtures of drug with an enteric coating and a gastric coating (instant claim 13).

Boyd teaches active ingredients such as penem antibiotics (see paragraph 0089) in particulate formulations surrounded by a coating (see paragraph 0114). The active ingredients may be without a functional coating (...conventional tablets with binders which dissolve in the stomach."), gastric coatings ("Coatings which dissolve at the pH of the stomach..."), enteric coatings ("Release only in the intestine is achieved using conventional enteric coatings...), or combinations thereof (see paragraph 0107).

While Boyd does not the ratio of instant claim 21, determination of such parameters are a matter of optimization or routine experimentation. Boyd explains that release throughout the gastrointestinal tract may be achieved by, e.g., pellets which dissolve at different pHs (see paragraph 0107).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a hard capsule in which an inorganic substance is contained with a penem antibiotic, wherein the drug is comprised of a functional coating mixture of gastric and enteric coating or a mixture of drug with and without functional coating as taught by Hasenzahl in view of Boyd. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it allows for release throughout the gastrointestinal tract, as explained by Boyd (see above).

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***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./  
Examiner, Art Unit 1615

/Humera N. Sheikh/  
Primary Examiner, Art Unit 1615